

INTERNATIONAL COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 23 November 2000 (23.11.00)	Applicant's or agent's file reference PATL010/PCT
International application No. PCT/US00/09493	Priority date (day/month/year) 13 April 1999 (13.04.99)
International filing date (day/month/year) 11 April 2000 (11.04.00)	
Applicant PATEL, Gordhanbhai, N.	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 03 November 2000 (03.11.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Antonia Muller Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PATL010/PCT	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 00/ 09493	International filing date (day/month/year) 11/04/2000	(Earliest) Priority Date (day/month/year) 13/04/1999
Applicant PATEL, Gordhanbhai, N.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No.

US 00/09493

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61L2/28 G01N31/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61L G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 58683 A (MINNESOTA MINING & MFG) 30 December 1998 (1998-12-30) page 4, line 3 -page 5, line 10 ---	1-18, 27-41
A	WO 98 52621 A (MINNESOTA MINING & MFG) 26 November 1998 (1998-11-26) ---	
A	US 4 407 960 A (TRATNYEK JOSEPH P) 4 October 1983 (1983-10-04) -----	

☐

Further documents are listed in the continuation of box C.

☒

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

27 July 2000

Date of mailing of the international search report

04/08/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Heck, G

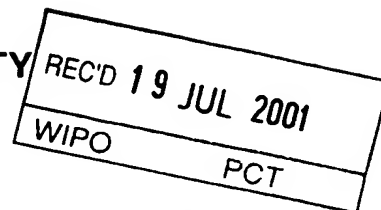
INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/09493

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 9858683	A	30-12-1998	AU	8174798 A		04-01-1999
			EP	0991432 A		12-04-2000
WO 9852621	A	26-11-1998	US	6063631 A		16-05-2000
			AU	7581498 A		11-12-1998
			EP	0984792 A		15-03-2000
US 4407960	A	04-10-1983	CA	1170551 A		10-07-1984



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PATL010/PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/09493	International filing date (day/month/year) 11/04/2000	Priority date (day/month/year) 13/04/1999
International Patent Classification (IPC) or national classification and IPC A61L2/28		
Applicant PATEL, Gordhanbhai, N.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 11 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 03/11/2000	Date of completion of this report 17.07.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Katsoulas, K Telephone No. +49 89 2399 8613 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/09493

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

5-18,22-31	as originally filed			
1-4,19-21	as received on	14/04/2001	with letter of	09/04/2001

Claims, No.:

9-18,30 (part), 31-38	as originally filed			
39	with telefax of	03/11/2000		
1-8,19-29,30 (part), 40,41	as received on	14/04/2001	with letter of	09/04/2001

Drawings, sheets:

1/4-4/4	as originally filed
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2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/09493

- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	10-14,22-29,33-36,38,39,41
	No:	Claims	1-9,15-21,30-32,37,40
Inventive step (IS)	Yes:	Claims	10-14,29
	No:	Claims	22-28,33-36,38,39,41
Industrial applicability (IA)	Yes:	Claims	1-41
	No:	Claims	

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

D1: WO98/58683; D2: WO98/52621

Ad Section V:

1. D1 discloses (cf. page 8 line 5) a device for monitoring plasma comprising a binder resin (polymer), having incorporated therein phenol red (indicator undergoing at least a colour change) and an alkali metal halide e.g. potassium bromide (activator) which, upon contact with plasma, undergoes halogenation and causes an indicator colour change from yellow to blue (page 4 lines 3-25, page 7 line 23). The polymer resin is soluble either in water or in a lower-alkyl alcohol (page 5 lines 7-9). Finally, the indicator can be pH-sensitive (page 8 line 29) and the activator can be a salt of an amine with an inorganic acid, such as tetra alkyl ammonium bromide.

Contrary to the comments of the applicant in the communication dated 09.04.2001, D1 contemplates the use of a monitor composition also on its own i.e. without any substrate (page 1 line 30) in a sterilisation process involving a plasma step (page 8 line 5). Thus, the composition (layer) is implicitly directly exposable to plasma. It follows that claims 1-9 and 15-21 are not new in view of the above disclosure (Art. 33(2) PCT).

2. Concerning the process claims, D1 discloses the use of a paper substrate to carry a solution of the monitor composition (cf. example 2), the substrate being part of a container for an item to be sterilised (page 14 lines 19-21). Thus, claims 30-32 are not new (Art. 33(2) PCT).
3. The device can be used to monitor sterilisation by affixing the device to the material to be sterilised (page 14, lines 12-18), the plasma being also derivable from hydrogen peroxide (page 14 line 5). Thus, claims 37 and 40 are not new in view of D1 (Art. 33(2) PCT).
4. D1 discloses the use of a plasma step in a sterilisation process which may involve a peracid (page 8 lines 5,6). Given that hydrogen peroxide is extensively used as a peracid in D1, it is considered as an obvious possibility to derive said plasma from hydrogen peroxide. Thus, claims 38, 39 and 41 lack an inventive step (Art. 33(3) PCT).

5. D2 discloses the provision of particular resins in the indicator composition to influence the penetration rate of hydrogen peroxide - generated plasma (page 7 lines 12-18) during sterilisation (page 4 lines 1-4). Thus, claim 24 lacks an inventive step in view of the combination of D1 and D2 (Art. 33(3) PCT).
6. The particular polymers according to claims 10-14, or the particular shape of the plasma permeable polymeric top layer according to claim 29 cannot be derived from the available art. They further succeed in solving the posed objective in a non-obvious manner. Thus, claims 10-14 and 29 meet the requirements of art. 33(3) PCT.

Ad Section VIII:

1. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
2. Contrary to the applicant's statement, no amended claims 30-39 were received with the submissions of 19.04.2001.
3. The paper by Paul T. Jacobs mentioned on page 2 of the applicant's submissions (letter of 19.04.2001) has not been supplied.